Aclaris Therapeutics Submits New Drug Application for A-101 as a Novel Treatment for Seborrheic Keratosis – a Common Skin Condition

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MALVERN, Pa., Feb. 27, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led, biotechnology company focused on defining new standards of care in medical and aesthetic dermatology, today announced it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for A-101 40% topical solution (A-101) as a treatment for seborrheic keratosis (SK). A-101, an investigational drug, is being developed by Aclaris as a non-invasive, in-office topical treatment for SK.

SK lesions are common, non-cancerous skin lesions that affect more than 83 million Americans. SK lesions can have a negative physical and emotional impact on patients because they may be perceived as cosmetically unattractive and associated with aging. Existing treatments are often painful, invasive and can have undesirable outcomes such as pigmentary changes or scarring. Fewer than 10% of people with SK lesions currently receive treatment.

Positive results from two pivotal Phase 3 trials – SEBK-301 and SEBK-302 – were reported in late 2016 and provide the clinical basis for this NDA submission. In these trials, A-101 met all primary and secondary endpoints, achieving clinically and statistically significant clearance of SK lesions. The two trials, which were identical in design and together enrolled 937 patients, evaluated the safety and efficacy of A-101 compared with vehicle (placebo) in patients with four target SK lesions on the face, trunk and extremities.

“This NDA submission represents a major step toward Aclaris’ goal of delivering a novel, topical treatment to address a significant unmet need in the dermatology market,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “If approved, we believe A-101 will have broad appeal across aesthetic and medical dermatology patients – both men and women.”

If approved, A-101 would be the first FDA-approved topical treatment for SK. Aclaris also plans to submit a marketing authorization application in the European Union in mid-2017.

About A-101

A-101 40% topical solution, an investigational drug, is a proprietary, high-concentration hydrogen peroxide formulation for the treatment of seborrheic keratosis (SK). It is being developed as a non-invasive, in-office treatment administered by physicians or other licensed health care professionals. In clinical trials, A-101 has been observed to have statistically and clinically significant results in clearing SK lesions with an adverse event profile similar to placebo. A-101 is designed to work by penetrating into the SK lesion and causing oxidative damage, which can ultimately result in the sloughing of the SK cells. A-101 has been the focus of a robust clinical development program in which over 700 patients have been treated with A-101. A higher concentration of A-101 is also in clinical development for the treatment of common warts (verruca vulgaris).

About Seborrheic Keratosis

Seborrheic keratosis (SK) is a skin condition that affects more than 83 million Americans and is characterized by non-cancerous lesions with a waxy, scaly, slightly elevated appearance that can vary in color from light tan to dark brown or black. SK lesions frequently appear in highly visible locations, such as the face or neck, and can have an adverse physical and emotional impact on people who have them. SK sufferers may be affected with just one lesion or dozens and often have a family history of SK. Prevalence of SK increases with advancing age and over three-quarters of patients seeking treatment from dermatologists are aged 40 to 69. SK is one of the most frequent diagnoses made by dermatologists, yet it remains undertreated. There are currently no FDA-approved medications for SK, and existing treatment procedures are often painful, invasive and can have undesirable outcomes like scarring or dyspigmentation.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biotechnology company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. Aclaris is based in Malvern, Pennsylvania.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding Aclaris' clinical development and potential regulatory approval for A-101. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in the Risk Factors section of Aclaris' Annual Report on Form 10-K for the year ended December 31, 2015, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "Financial Information" section of the Investors page of Aclaris' website at http://www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

Contact:
Aclaris Contact
Michael Tung, M.D.
Investor Relations
484-329-2140
mtung@aclaristx.com

Media Contact
Mariann Caprino
TogoRun
917-242-1087
M.Caprino@togorun.com

Aclaris Therapeutics, Inc.